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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,848	02/02/2006	Hao Li	4-32776A	8615

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CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
LONG, SCOTT	
ART UNIT	PAPER NUMBER
1633	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	04/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/537,848	LI, HAO	
	Examiner	Art Unit	
	Scott D. Long	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-57* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-18, 40-49, drawn to a method to treatment, prevent, ameliorate pathological conditions associated with dysregulation of the insulin signaling pathway comprising administering to a subject in need thereof an effective amount of a modulator of a protein selected from the group consisting of those disclosed in Table 4 or Table5, classified in class 536, subclass 23.1 and class 424, subclass 130.1.

With the election of group I, a further restriction among the various proteins set forth in Tables 4 and 5 is required as set forth below:

Applicants must elect from groups 1-90, wherein groups 1-90 correspond to a unique protein target set forth in tables 4 and 5 respectively.

Group II, claim(s) 19-28, drawn to a method to identify modulators useful to treat, prevent, ameliorate pathological conditions associated with dysregulation of the insulin signaling pathway comprising assaying modulatory capacity of modulator of a protein selected from the group consisting of those disclosed in Table 4 or Table 5, classified in class 536, subclass 23.1 and class 424, subclass 130.1.

With the election of group II, a further restriction among the various proteins set forth in Tables 4 and 5 is required as set forth below:

Applicants must elect from groups 91-180, wherein groups 91-180 correspond to a unique protein target set forth in tables 4 and 5 respectively.

Group III, claim(s) 29-37, drawn to a pharmaceutical composition comprising modulator to a protein selected from the group consisting of those disclosed in Table 4 or Table 5, class 424, subclass 130.1.

With the election of group III, a further restriction among the various proteins set forth in Tables 4 and 5 is required as set forth below:

Applicants must elect from groups III, wherein groups 29-37 correspond to a unique protein target set forth in tables 4 and 5 respectively.

Group IV, claim(s) 38, drawn to method to diagnose with modulators of mRNA of a protein selected from the group consisting of those disclosed in Table 4 or Table 5, classified in class 536, subclass 23.1

With the election of group IV, a further restriction among the various proteins set forth in Tables 4 and 5 is required as set forth below:

Applicants must elect from groups 38, wherein groups 1-90 correspond to a unique protein target set forth in tables 4 and 5 respectively.

Group V, claim(s) 39, drawn to method to diagnose with protein modulators of a protein selected from the group consisting of those disclosed in Table 4 or Table 5, classified in class 424, subclass 130.1.

With the election of group V, a further restriction among the various proteins set forth in Tables 4 and 5 is required as set forth below:

Applicants must elect from groups 39, wherein groups 1-90 correspond to a unique protein target set forth in tables 4 and 5 respectively.

Group VI, claim(s) 50, drawn to a diagnostic kit for detecting mRNA levels of a protein selected from the group consisting of those disclosed in Table 4 or Table 5 and administrating controls, classified in class 536, subclass 23.1.

With the election of group VI, a further restriction among the various proteins set forth in Tables 4 and 5 is required as set forth below:

Applicants must elect from groups 50, wherein groups 1-90 correspond to a unique protein target set forth in tables 4 and 5 respectively.

Groups VII, claim(s) 51, drawn to a diagnostic kit for detecting protein levels of a protein selected from the group consisting of those disclosed in Table 4 or Table 5 and administrating controls, classified in class 424, subclass 130.1.

With the election of group VII, a further restriction among the various proteins set forth in Tables 4 and 5 is required as set forth below:

Applicants must elect from groups 51, wherein groups 1-90 correspond to a unique protein target set forth in tables 4 and 5 respectively.

Groups VIII, claim(s) 52-57, drawn to method to method to identify genetic modifiers of the insulin signaling pathway comprising use of transgenic flies, classified in class 800, subclass 3.

With the election of group VII, a further restriction among the various proteins set forth in Tables 4 and 5 is required as set forth below:

Applicants must elect from groups VIII, wherein groups 1-90 correspond to a unique protein target set forth in tables 4 and 5 respectively.

The inventions listed as Groups 1-811 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons:

> 37 CFR 1.475(c) states:
> "If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present."
>
> 37 CFR 1.47(d) also states:
> "If multiple products, processes of manufacture, or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT article 17(3)(a) and 1.476(c)."

In the instant application, Groups II, IV, V, and VIII constitute additional methods distinct from Group I. Groups III, VI and VII constitute additional products distinct from Group I. Accordingly, restriction of Groups I-VIII is proper.

The technical feature of Group I-1 is drawn to a method to treatment, prevent, ameliorate pathological conditions associated with dysregulation of the insulin signaling pathway comprising administering to a subject in need thereof an effective amount of a modulator of FMR2 protein. The method of treatment which comprises administering a

modulator of FMR2 which is structurally and materially distinct from modulators of groups II-IX, further demonstrating the physical distinctness of the modulators in these methods. A search for modulators of FMR2 (group I-1) would not be co-extensive with a search for modulators of nucleoside diphosphatase (EU-UDPase) (group I-2), for example. Further, a reference rendering *FMR2* as anticipated or obvious over the prior art would not necessarily also render nucleoside diphosphatase (EU-UDPase) as anticipated or obvious over the prior art. Thus, a search and examination of anything beyond any of the groups as set forth above would be unduly burdensome to the examiner.

2. Should Applicant elect any of Inventions I and III, a further group restriction is required under 35 U.S.C. 121 and 372. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Each Invention detailed above reads on patentably distinct inventive groups drawn to various methods and pharmaceutical compositions. According to PCT Rule 13.2 and to the guidelines in Section (f)(i)(A) of Annex B of the PCT Administrative Instructions, all alternatives of a Markush Group must have a common property or activity. The compounds recited in Claims 5 and 8, 14 and 17, 33 and 36, do not have a common structure in that they comprise various antibodies and nucleic acids with

different functions and structures, the compositions and methods are not regarded as being of similar nature because all of the alternatives do not share a common property or activity. The compositions and methods of Claims 5 and 8, 14 and 17, 33 and 36, do not share a common core structure or function, thus the inventions are patentably distinct. A search for a FMR2 RNAi would not be co-extensive with a search for an antibody immunoreactive against FRM2, for example.

In response to the group restriction requirement, **Applicant must further elect either an antibody or a single type of nucleic acid** as described in claim 8, for example.

Response Requirement

3. Applicant is advised that the reply to this requirement to be complete must include (i) an election of an invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Multiple Inventors

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Examiner Contact Information

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Scott Long** whose telephone number is **571-272-9048**. The examiner can normally be reached on Monday - Friday, 9am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Woitach**, can be reached on **571-272-0739**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Scott Long
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